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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,331	08/04/2003	Alan J. Polito	7035-0003.03	6774

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/634,331	Applicant(s) POLITO ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-116 is/are pending in the application.
- 4a) Of the above claim(s) 107-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 98-116 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on December 20, 2004 is acknowledged. The traversal is on the ground(s) that the inventions are adequately related and that there would be no serious search burden in searching the additional groups. This argument is not found persuasive because the inventions are distinct and unrelated, each from the other because of the reasons previously provided. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods are distinct as claimed because they have different methods steps; different functions and the effects have different final outcomes. Moreover, the different inventions are drawn to unrelated apparatus and methods, and in view of the different components and the different modes of operation the inventions are deemed distinct.

Applicants' argue that there would be no serious burden on the Examiner to search for the other groups. However, in the instant case these inventions are unrelated and distinct. The methods are distinct as claimed because they are drawn to measuring or performing different activities. Furthermore the distinct steps and products require separate and distinct searches. The groups have a separate status in the art as shown by their different classification. As such, it would be burdensome to search the inventions of groups together. Furthermore, a search for the invention of the groups would not be coextensive because a

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search indicating the process of one is novel or unobvious would not extend to a holding that the process of the other is novel or unobvious. Because of the different classifications of each group based upon the distinct method steps, a serious burden is imposed on the examiner to perform a complete search of the defined areas in both the patent and non-patent literature. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden on the examination of this application.

Applicants' argument that the groups are not distinct is not found persuasive because contrary to applicants arguments the inventions have been shown to be distinct in view of: distinct apparatus; the different methods that require different components; and the different capabilities of those methods as compared to the other groups. Contrary to applicants' arguments drawn to the classification being in the same class, each group has been shown to form a separate subject for inventive effort with an explanation indicates recognition of separate inventive effort by inventors. Also each distinct group shows the need for a separate field of search. Thus applicants' arguments are not persuasive since each group has been shown to be distinct. Therefore applicants' argument that the search is not burdensome is not persuasive. The requirement is still deemed proper and is therefore made FINAL.

Amendment Entry

2. The Office Action, dated August 24, 2004 has been withdrawn in view of applicants' amendments. Claims 1-97 have been cancelled. Claims 98-116 have been newly added. Claims 107-116 have been withdrawn from consideration. Therefore, only claims 98-106 are under consideration in this office action.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Priority

4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now abandoned" should follow the filing date of application 09/638,668.

Claim Objections

5. Claims 100 and 102-106 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are drawn to an apparatus, however claim 100 does not provide any additional structural limitations to the apparatus, rather it is drawn to quantitation of the analyte. Similarly, claims 102-106 are drawn to the sample types and fail to further limit the structural components of the apparatus. Therefore the claims are objected too.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 100 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 100 recites the limitation "the detection of the analyte" in the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 100 and 102-106 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the

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necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: that there is no structural relationship between the claimed apparatus and the apparatus' ability to quantitate analyte. Similarly, claims 102-106 are drawn to the sample types and fail to further limit the structural components of the apparatus. Therefore the claims are rejected and clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 98-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Zweig (US Patent 5,554,531). The claims are drawn to an apparatus comprising a housing and an autostart means. The dependant claims are drawn to the apparatus further comprising a heating element and test strip. The dependant claims are also drawn to the type of biological or non-biological samples.

Zweig (US Patent 5,554,531) teaches a detection unit apparatus for performing timed assays under temperature control using a heating element, whereby detection occurs by optical determination of a change in the test article resulting from presence of analyte in the sample over time (col. 2 lines 55-63).

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The apparatus includes a test article comprising a bibulous matrix having one or more dried reagents therein (col. 3 lines 5-9). The apparatus therefore comprises a bibulous matrix structure, typically in the form of a flat membrane; a support structure; and an electrode structure (col. 5 lines 10-54). Thus the test article acts as the housing, and the support structure meets the instantly claimed limitations of having a receptacle for retaining a test strip. The art also teaches having polystyrene strips within the support, which meet the limitations for an apparatus comprising a test strip (col. 8 lines 1-5). A pair of spaced apart electrodes is also employed thereby allowing for initial sample application to be detected (col. 3 lines 7-14). Therefore, the apparatus comprises a capacitance sensor that senses the application of sample, thereby meeting the autostart limitation. The detection unit comprises a heating element, for heating the test article approximate to the reaction zone (col. 3 lines 63-65). Figure 2 shows a detection unit housing including plates which contact electrodes wherein the plates may have heating coils on their surface (col. 8 lines 45-63). The apparatus uses patient specimens, such as blood, serum, plasma, urine, industrial, environmental and food samples (col. 4 lines 50-57). Thus, the prior art teaches using both non-biological and biological samples, just as instantly claimed.

It is the examiner's position that the claims recite intended use for the components of the claimed apparatus. The intended use of the biological samples is not viewed as having structural limitations. Only the actual component, i.e., the housing and housing means are considered to have structural limitations. The prior art structures are taught thus the art meets the claim.

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Accordingly, the apparatus of Zweig (US Patent 5,554,531) teach an apparatus for conducting a lateral flow assay on a test strip for detection of an analyte in a sample comprising a housing; an autostart means; heating element; and test strip.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 98-101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, and 5-8 of U.S. Patent No. 6,136,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a memory comprising instructions.

The claims of US Patent 6,136,610 are drawn to an apparatus comprising a housing with a receptacle for retaining a test strip with the test strip comprising a means for the determining the amount of analyte. The apparatus further

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comprises a heating element, electrical leads that form a capacitor that initiate timing of the assay for the addition of sample to the test strip, thereby meeting the autostart limitation.

Both the instant claims and the claims of the US Patent are drawn to same elements, i.e., the a housing, an autostart means, a heating element, and test strip components. The open language of the instant claims embraces the apparatus of US Patent 6,136,610. Therefore, the apparatus claimed within US Patent 6,136,610 comprises the same components which perform the same functions as those instantly recited within the claims; thus the instant claims are rejected.

Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rylatt et al., (WO 97/09620) teach quantitative determination of analyte concentration by instrument reading of test devices.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

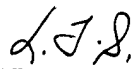
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
March 7, 2005


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1601